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AUG 2 4 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K110776

1. **Submitter's Identification:**

Name: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.
Address: Building 2, No.202, Zhenzhong Road, West Lake Economy &. Technology Zone, 310030 Hangzhou, China

2. **Information of the Device:**

Name of the Device:	Digital thermometer MT Series
Including:	Digital Thermometer Model MT-101D, MT-101M, MT-101P, MT-101R, MT-111, MT-111R, MT-1019; MT-201R, MT-2019, MT-2121; MT-402S, MT-4218, MT-4220, MT-4223; MT-401, MT-401A, MT-401P, MT-401R, MT-4119, MT-4121, MT-403S, MT-4318, MT-4320,MT-4323, MT-4625
Classification name:	Clinical Electronic Thermometer (per CFR 880.2910)
Class:	II
Panel:	80
Product code:	FLL- Clinical Electronic Thermometer

3. **Information of Predicate Device:**

* DIGITAL THERMOMETER MODEL MT-101
510(k) number: K051699
Applicant: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.
Owner: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

The medical grade plastics that mold the enclosures and the probe head are made of ABS and stainless steel.

* DIGITAL THERMOMETER MODEL MT SERIES
510(k) number: K062784
Applicant: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.
Owner: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

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4. **Device Description:**

Digital Thermometer MT series enable fast and reliable measurements. These thermometers provide very high clinical accuracy, and have been designed to provide maximum user-friendliness. Digital Thermometer MT series can be used in conjunction with or without a disposable probe cover, when preferred.
The basic principle of these thermometers is that a change of thermistor resistance, caused by changes of temperature, is converted to changes of frequency of R-C oscillator circuit. Therefore, temperature can be given by measuring the frequency of the oscillator.
For a given time period by applying to R-C oscillator circuit, changes of temperature will correspond to changes of pulse number.

5. **Intended Use:**

Digital Thermometer MT series are intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the devices are reusable for clinical or home use on people of all ages.

6. **Comparison to Predicate Devices:**

The device models MT-101D, MT-101M, MT-101P, MT-101R, MT-111, MT-111R, MT-1019 are similar in design and intended use to the DIGITAL THERMOMETER MODEL MT-101, differing only in physical dimensions.

The device models MT-201R, MT-2019, MT-2121 are similar in design and intended use to the MT-201 of DIGITAL THERMOMETER MODEL MT SERIES, differing only in physical dimensions.

The device models MT-402S, MT-4218, MT-4220, MT-4223 are similar in design and intended use to the MT-402 of DIGITAL THERMOMETER MODEL MT SERIES, differing only in physical dimensions.

The device models MT-401, MT-401A, MT-401P, MT-401R, MT-4119, MT-4121, MT-403S, MT-4318, MT-4320, MT-4323, MT-4625 are similar in design and intended use to the MT-403 of DIGITAL THERMOMETER MODEL MT SERIES, differing only in physical dimensions. And MT-401, MT-401A, MT-401P, MT-401R, MT-4119, MT-4121 are rigid tip, MT-403 flexible tip.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E 1 112, as well as IEC60601-1, IEC60601-1-2 and ISO10993-1 requirements.

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Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers."

8. **Discussion of Clinical Tests Performed:**

Controlled human clinical studies were conducted using the digital thermometer MT series. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Sejoy Clinical Test Protocol outline.

9. **Conclusions:**

The digital thermometer MT series with all corresponding Models have the same intended use and similar technological characteristics as the cleared devices of DIGITAL THERMOMETER MODEL MT-101(K051699) and DIGITAL THERMOMETER MODEL MT SERIES (K062784).
Moreover, verification and validation tests contained in this submission clearly demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness. Furthermore, those engineering differences do not affect the intended use or alter the fundamental scientific technology of the cleared devices of DIGITAL THERMOMETER MODEL MT-101(K051699) and DIGITAL THERMOMETER MODEL MT SERIES(K062784).

Thus, the digital thermometer MT series with all corresponding Models are substantially equivalent to the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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China 310030

AUG 2 4 2011

Re: K110776
Trade/Device Name: Digital Thermometer MT series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 15, 2011
Received: July 26, 2011

Dear Mr. Yen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110776

Indications for Use

510(k) Number (if known):

Device Name: Digital Thermometer MT series

Indications For Use:

The digital thermometers MT series are intended to measure the human body temperature in regular mode orally, rectally or under the arm. The devices are reusable for clinical or home use on people of all ages.

Prescription Use_____ **AND/OR** **Over-The-Counter Use** √

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110776